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INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT Article 36 and Rule 70)

Applicant's or agent's file reference 15228-33PCT PTN/df		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/CA 03/01542	International filing date (day/month/year) 06.10.2003	Priority date (day/month/year) 04.10.2002	
International Patent Classification (IPC) or both national classification and IPC A61B19/00			
Applicant ORTHOSOFT INC. et al.			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
 - ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 1 sheets.

3. This report contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

Date of submission of the demand 28.04.2004	Date of completion of this report 28.10.2004
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**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/CA 03/01542**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-14 as originally filed

Claims, Numbers

1, 2, 3 (part), 7 (part), 8-20 as originally filed
3 (part), 4-6, 7 (part) received on 06.10.2004 with letter of 01.10.2004

Drawings, Sheets

1/3-3/3 received on 08.01.2004 with letter of 05.12.2003

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 7-14

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 7-14

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	2,5,15-20
	No: Claims	1,3,4,6
Inventive step (IS)	Yes: Claims	
	No: Claims	1-6,15-20
Industrial applicability (IA)	Yes: Claims	1-6,15-20
	No: Claims	

2. Citations and explanations

see separate sheet

1. Reference is made to the following documents:

D1: WO-A-02/062250

D2: DE-U-200 16 635

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

2. The document D1 discloses (the references in parentheses applying to this document):

A computer-assisted surgery system (page 6, line 4) for guiding an operator in altering a pelvis for a subsequent insertion of a pelvic implant, comprising:
A sensing apparatus (page 6, line 17, reference 15) adapted to track a reference tool securable to the pelvis and a bone altering tool for position and orientation;
A position calculator (page 6, lines 19-25) connected to the sensing apparatus for calculating a position and orientation of a pelvic frame of reference as a function of the position and orientation of the reference tool (page 7, paragraph 4), and for calculating a position and orientation of the bone altering tool with respect to the frame of reference when altering the pelvis;
a source of posture data (page 3, lines 24-29);
a posture data correction calculator (page 3, lines 28-32) operative to provide a display of information allowing an operator to take into consideration said posture data from the source of posture data when altering the pelvis; and
a display unit (page 3, lines 28-32) connected to the position calculator and to the posture data correction calculator for displaying said display of information and the position and orientation of the bone altering tool with respect to the pelvic frame of reference.

Hence, the subject-matter of claim 1 is not regarded as being new (Article 33(2) PCT).

2. The subject-matter of claim 2 is not regarded as involving an inventive step (Article 33(3) PCT), as it is current practice for a person skilled in the art to display corrected views during image guided surgery.
3. The subject-matter of claims 3 and 4 is not regarded as being new (Article 33(2)

PCT) for the following reason: Anteversion and inclination values are displayed in D1 (page 8, paragraph 6).

4. The subject-matter of claim 5 is not regarded as involving an inventive step (Article 33(3) PCT) for the following reason: D2 shows a system for navigation-assisted alignment of elements. Posture data is being stored with supplementary information comprising the position of the table on which a patient is lying. The position of the table is being regarded as defining a plane supporting the patient in a given posture with respect to the frame of reference. Hence, a person skilled in the art would digitize an absolute reference plane (e.g. an operating table surface), which is already done in D1 (see page 7, paragraph 2) and save it together with the image (see D2, page 9, paragraph 2) in order to be able to combine the image with further images taken e.g. from different limbs. Although, in the case of the present application, the supplementary information is used for combining different images taken from one patient, the data as stored in D2 can also be used for comparing posture data from different patients.
5. The subject-matter of claim 6 is not new (Article 33(2)), as D1 shows a computer comprising code means for executing the functions as e.g. stated in claim 1.
6. Because of the reasons already given in the paragraph 4, the subject-matter of claims 15-20 is not regarded as being inventive (Article 33(3) PCT). Further, the points used for defining a reference frame are also the anterior-superior iliac spines and pubic tubercles (see D1, page 7, paragraph 2).
7. The subject-matter of claims 1-6 and 15-20 are industrially applicable (Article 33(4) PCT).

Re Item VII

Certain defects in the international application

8. The "frame of reference" does not seem to have an antecedent, whereas the definite article is used (Article 6 PCT).

information is additional information relating the frame of reference to said posture data.

4. The computer-assisted surgery system according to claim 3, wherein said additional
5 information includes an anteversion value and an inclination value of the bone altering tool related to said posture data.

5. The computer-assisted surgery system according to any one of claims 1 to 5, wherein the
10 source of posture data is a registration tool trackable for position and orientation, the registration tool being used with the position calculator to digitize a plane supporting the patient in a given posture with respect to the frame of
15 reference, said posture data being associated with an orientation of said plane.

6. A posture data correction calculator program product comprising code means recorded in a computer-readable memory for executing functions of
20 the posture data correction calculator defined in any one of claims 1 to 5.

7. A method for guiding an operator in altering a pelvis for a subsequent insertion of a pelvic implant in computer-assisted surgery,
25 comprising the steps of:

creating a frame of reference related to geometry information of a pelvis, the frame of reference being trackable for position and orientation;